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This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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22582 U.S. PTO 60/514355 102403

TITLE OF THE INVENTION (280 characters max)

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ENCLOSED APPLICATION PARTS *(check all that apply)*

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☐ Application Data Sheet. See 37 CFR 1.76			

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

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Respectfully submitted,

SIGNATURE

Date 10/24/2003

REGISTRATION NO. 38,755
(if appropriate)

TYPED or PRINTED NAME James R. Stevenson

Docket Number: VI/03-012.P

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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Invention: **SYSTEMS FOR DETECTING EXTRAVASATION AND SENSOR DEVICES THEREFOR**

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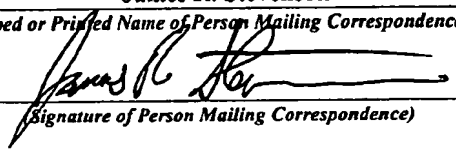

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SYSTEMS FOR DETECTING EXTRAVASATION AND SENSOR DEVICES THEREFOR

FIELD OF THE INVENTION

[01] The present invention relates generally to the detection of fluid and/or other material in tissue. More particularly, the invention pertains to systems, methods and/or devices for detecting whether the level of fluid in tissue has changed, particularly if the fluid level has increased or has otherwise become abnormal.

BRIEF DESCRIPTION OF RELATED ART

[02] The following information is provided to assist the reader to understand the invention disclosed below and the environment in which it will typically be used. The terms used herein are not intended to be limited to any particular narrow interpretation unless clearly stated otherwise in this document.

[03] Changed, elevated or abnormal fluid levels in living tissue can result from a number of physiological conditions. For example, edema is an abnormal accumulation of watery fluid in the intercellular spaces of connective tissue. Edematous tissues are swollen and, when punctured, secrete a thin incoagulable fluid. Edema is most frequently a symptom of disease rather than a disease in itself, and it may have a number of causes, most of which can be traced back to gross variations in the physiological mechanisms that normally maintain a constant water balance in the cells, tissues, and blood. Among the causes may be diseases of the kidneys, heart, veins, or lymphatic system; malnutrition; or allergic reactions.

[04] Moreover, bleeding (hemorrhage) can cause blood to collect and clot (hematoma). Hematomas can, for example, occur beneath the outermost of three membranes that cover the brain (meninges) as a result of a head injury. There are two types of cranial subdural hematomas. An acute subdural hematoma occurs soon after a severe head injury. A chronic subdural hematoma is a complication that may develop weeks after a head injury.

Such a head injury may have been so minor that the patient does not remember it. An epidural hematoma is a traumatic accumulation of blood between the inner table of the skull and the stripped-off dural membrane. The inciting event often is a focused blow to the head. It is often difficult to detect hematomas, particularly when the hematoma occurs well after the time of an injury.

[05] In addition to accumulation of body fluids, elevated fluid levels in tissue can arise as a result of introduction of a fluid into the body, for example, during an injection procedure. In that regard, in many medical diagnostic and therapeutic procedures, a physician or other person injects fluid into a patient's blood vessels. Moreover, in recent years, a number of injector-actuated syringes and powered injectors for pressurized injection of contrast medium in procedures such as angiography, computed tomography, ultrasound and NMR/MRI have been developed.

[06] Extravasation or infiltration is the accidental infusion or leakage of an injection fluid such as a contrast medium or a therapeutic agent into tissue surrounding a blood vessel rather than into the blood vessel itself. Extravasation can be caused, for example, by rupture or dissection of fragile vasculature, valve disease, inappropriate needle placement, or patient movement resulting in the infusing needle being pulled from the intended vessel or causing the needle to be pushed through the wall of the vessel. High injection pressures and/or rates of some modern procedures can increase the risk of extravasation. In computed tomography, for example, contrast injection flow rates can be in the range of 0.1 to 10 ml/s.

[07] Extravasation can cause serious injury to patients. In that regard, certain injection fluids such as contrast media or chemotherapy drugs can be toxic to tissue. It is, therefore, very important when performing fluid injections to detect extravasation as soon as possible and discontinue the injection upon detection.

[08] Several extravasation detection techniques are known in the art. Two simple and very useful techniques for detecting extravasation are palpation of the patient in the vicinity of the injection site and simple visual observation of the vicinity of the injection site by a trained health care provider. In the palpation technique, the health care provider manually

senses swelling of tissue near the injection site resulting from extravasation. By visual observation, it is also sometimes possible to observe directly any swelling of the skin in the vicinity of an injection site resulting from extravasation.

[09] In addition to palpation and observation, there are a number of automated methods of detecting extravasation that may include automatic triggering of an alarm condition upon detection. Unfortunately, each of these automated methods of detecting extravasation is limited by significant drawbacks.

[10] In that regard, several plethysmographic detection techniques are available. For example, mercury strain gauge plethysmographs measure the volume change resulting from venous blood flow in a cross sectional area of a limb of a patient. Air cuff or pulse volume recorder plethysmographs measure the changes in pressure within a recording cuff. Such plethysmographs can be cumbersome to operate and/or insensitive to small changes in volume.

[11] Impedance plethysmographs use low-frequency electromagnetic energy transmitted via galvanic contact with the skin to measure changes in the electrical impedance in a defined tissue volume of a limb. Detection of extravasation via impedance changes is disclosed, for example, in U.S. Patents 5,964,703 and 5,947,910. In this method, an impedance change of a certain level relative to a baseline measurement in the vicinity of the injection site is interpreted as being an extravasation. A change in impedance occurs during extravasation because injection fluid in the tissue of the patient changes both the volume and the electrical impedance properties of the tissue. Use of electrodes in impedance plethysmographs can, however, result in instabilities. For example, maintaining suitable electrical (ohmic or galvanic) contact between the electrodes of impedance plethysmographs and the skin of the patient is often very difficult.

[12] Photo-plethysmographs measure the optical scattering properties of capillary blood to detect the presence of extravasated fluids in tissue. An example of a photo-plethysmograph is described in U.S. Patent 4,877,034. Because light is heavily absorbed in tissue, however, the sensitivity of photo-plethysmographs is generally limited to the top 1/4 inch of tissue. Many extravasations, however, occur deeper than 1/4 inch. Moreover,

the injection medium may flow into interstitial spaces remote from the photoplethysmograph sensors and go undetected.

[13] A number of extravasation detection devices attempt to measure temperature differences to determine if an extravasation has occurred. For example, U.S. Patent 4,647,281 discloses subcutaneous temperature sensing of extravasation to trigger an alarm. In this method of extravasation detection, an antenna and a microwave radiometer instantaneously measure the temperature of the subcutaneous tissue at the site where fluid is injected by measuring microwave radiation emitted naturally from the body. An algorithm periodically determines the temperature difference between tissue and injected fluid, and compares the difference to a fixed threshold. An alarm processor uses the comparison to determine an alarm condition.

[14] In addition, U.S. Patent 5,334,141 discloses a microwave extravasation detection system employing a reusable microwave antenna and a disposable attachment element for releasably securing the microwave antenna to a patient's skin over an injection site. The attachment element holds the antenna in intimate contact with the patient's skin to optimize microwave transfer therebetween, while shielding the antenna from environmental noise signals. U.S. Patent 5,954,668 also discloses use of a microwave antenna to sense temperature of tissue to detect extravasation. Although measurement of temperature changes and emissivity using microwave energy can result in instantaneous detection, temperature differences are often too small for practical measurement.

[15] In addition to microwave radiometry for the detection of extravasation as described above, radiometry has also been proposed for the detection of pulmonary edema as described in U.S. Patent 4,488,559. U.S. Patent 4,240,445 discloses detection of pulmonary edema via transmitting electromagnetic energy through a transmission line coupled to tissue. U.S. Patent 4,690,149 discloses detection of brain edema via impedance changes detected by a sensor. A proposed method of detection of brain edema is also disclosed in U.S. Patent 6,233,479, in which a measured signal from a microwave antenna is compared to a stored characteristic edema signal.

[16] Microwave energy has also been used for the detection of tumors in living tissue as described in U.S. Patent 6,061,589. Unlike the passive measurements in microwave radiometry, U.S. Patent 6,061,589 disclosed transmission of electromagnetic energy into the body (breast tissue) using a microwave antenna in and a resultant signal is measured. In that regard, U.S. Patent 6,061,589 describes a microwave antenna to detect incipient tumors in accordance with differences in relative dielectric characteristics. Electromagnetic energy in the microwave frequency range is applied to a discrete volume in the tissue and scattered signal returns are collected. The irradiated location is shifted or changed in a predetermined scanning pattern. The returned signals are processed to detect anomalies indicative of the present of a tumor.

[17] Likewise, microwave energy has been proposed for use in water content mapping in human tissue as described in U.S. Patent 5,995,863. Microwave energy has also been used as in non-invasive tomographic spectroscopy imaging. See U.S. Patent 6,332,087 and 6,026,173.

[18] Microwave energy has further been used to measure the fat content in nonliving organic tissue. For example, M. Kent, "Hand Held Fat/Water Determination", (1993), available at www.distell.com/products/papers/pap- er2.htm, discloses a microstrip sensor for such a determination. In general, the fat content of pelagic and other fatty species of fish is proportion to water content. The dielectric properties of the fish depend on the water content. In the device of Kent, changes in transmission properties of the fish were calibrated against water content.

[19] It is very desirable to develop improved devices, systems and methods for detecting elevated or otherwise abnormal levels of fluids in living tissue (for example, as a result of edema, hematoma or extravasation). The objectives and advantages of the invention herein presented will become fully apparent to persons skilled in the relevant art from a reading of the detailed description section of this document, and will become particularly apparent when the detailed description is considered along with the drawings and claims presented herein.

SUMMARY OF THE INVENTION

[20] The objectives and advantages of the invention are attained by the various embodiments and related aspects of the invention summarized below.

[21] In one presently preferred embodiment, the invention provides a sensor device capable of detecting changes in the level of fluid within tissue of a body. The sensor device includes a housing, a substrate, and a plurality of antenna elements. The housing has a plurality of bridge segments that are arranged to circumscribe an opening defined by the housing. The substrate is mounted within the housing at least at an intersection of each of the bridge segments. Each of the antenna elements at a base thereof is accommodated by and mounted to the substrate at each of the intersections of the bridge segments and at an outer surface thereof faces away from the substrate. The housing extends to the outer surfaces of the antenna elements and an electrical shield surrounds each of the antenna elements except for the outer surfaces thereof.

[22] In a related embodiment, the invention provides a system for wirelessly communicating a change in the level of fluid within tissue of a body. The system includes a sensor device, a transmitter, and a remote receiver. The sensor device is used for detecting a change in the level of fluid within the tissue. Connected to the sensor device, the transmitter is used to receive therefrom an indication of the change in the level of fluid within the tissue and to transmit a radio frequency signal indicative thereof. The remote receiver is used to receive the radio frequency signal(s) transmitted by the transmitter and to provide a warning alert thereupon.

[23] In a related aspect, the invention also provides an attachment mechanism for use in attaching a sensing device to the skin of a patient. The attachment mechanism includes an adhesive portion and a release band. The adhesive portion has one side thereof coated with a first adhesive capable of removably attaching to the skin and an opposite side thereof coated with a second adhesive capable of attaching to a bottom surface of the sensing device. The release band is affixed to a perimeter of the adhesive portion to enable the attachment mechanism, and the sensing device therewith, to be removed from the skin. For sensing devices defining an opening through which access is provided to the

skin, the adhesive portion can define a cutout region generally coextensive with the opening defined by the sensing device.

BRIEF DESCRIPTION OF THE DRAWINGS

[24] The invention, and particularly its presently preferred and alternative embodiments and related aspects, will be better understood by reference to the detailed disclosure below and to the accompanying drawings, in which:

[25] **Figure 1A** illustrates a perspective view of an extravasation sensor according to a presently preferred embodiment of the invention, showing the antennae on a bottom surface thereof designed for contact with the skin of a patient and the RF cable assemblies associated therewith.

[26] **Figure 1B** is a bottom view of the extravasation sensor shown in Figure 1A.

[27] **Figure 1C** is a side view of the extravasation sensor shown in Figure 1A, with the bottom surface thereof facing towards the bottom of the page.

[28] **Figure 1D** is a top view of the extravasation sensor shown in Figure 1A.

[29] **Figure 1E** is an end view of the extravasation sensor shown in Figure 1A, with the bottom surface thereof facing towards the bottom of the page.

[30] **Figure 2** illustrates a generalized structural layout of the present invention, showing the active and dead zones of an extravasation sensor such as the one shown in Figure 1A.

[31] **Figure 3** depicts one possible layout for a flexible circuit board, showing flexible striplines for use in conveying signals to and from the antennas of an extravasation sensor such as the one shown in Figure 1A.

[32] **Figure 4** illustrates a step-by-step procedure for using an attachment mechanism to attach an extravasation sensor of the present invention to the skin of a patient.

[33] **Figure 5** illustrates an extravasation sensor attached to the patient via the attachment mechanism of Figure 4 and its use within a control room of an imaging suite.

[34] **Figure 6A** illustrates an extravasation sensor according to the present invention with which light pipes and associated indicators are used to provide a visual indication of extravasation.

[35] **Figure 6B** illustrates an extravasation sensor according to the present invention into which an arm button has been incorporated and which doubles as a visual indicator of extravasation.

[36] **Figure 6C** illustrates an extravasation sensor according to the present invention into which an indicator has been incorporated into each antenna element as a visual indicator of extravasation.

[37] **Figure 7** illustrates a system for wirelessly transmitting a signal indicative of extravasation, detected by an extravasation sensor such as the one shown in Figure 1A, to a remote receiver therefor.

DETAILED DESCRIPTION OF THE INVENTION

[38] While the sensors, systems and methods of the present invention are generally applicable to the sensing any fluid within body tissue (whether a body fluid or an introduced fluid), the present invention is primarily described herein with reference to the representative example of extravasation of a fluid intended to be injected into a vascular structure. One skilled in the art will appreciate, however, that elevated, abnormal or changing levels of generally any fluid can be detected using the sensors, systems and methods of the present invention. Detection of body fluids in the present invention includes, but is not limited to, the detection of fluid changes as a result of edema, hematoma, ruptured bowel and colostomy tubing leakage into the peritoneal cavity. Introduced or foreign fluid detectible in the present invention include fluid introduced via generally any technique known in the medical arts including, but not limited to, injection, infusion and IV drip. As described above, changes in complex permittivity and permeability as a result of changing fluid levels in tissue are detected by application of electromagnetic energy to the tissue and detection of a resultant signal.

[39] Complex permittivity and permeability govern how an electromagnetic wave will propagate through a substance. Complex permittivity typically has the greatest effect since it varies significantly between tissue types and fluids of interest. The complex permeability of various tissues and many fluids of interest is approximately that of a vacuum, reducing the effect of this parameter. Some fluids, however, such as MRI contrast agents may have an appreciable complex permeability difference from tissue. Although blood contains small amounts of iron, the permeability value for any significant volume of blood is typically insignificant. Complex permittivity is generally expressed as:

$$\epsilon^*=\epsilon'-j\epsilon''$$

[40] wherein ϵ' is the real component of the complex value and is known as the dielectric constant or sometimes simply referred to as the "permittivity." The term ϵ'' is the imaginary component of the complex value and is often referred to as the "loss factor." The ratio of (ϵ''/ϵ') is known as the "loss tangent." The complex permittivity (and sometimes permeability) of certain substances differ from the body tissue at certain frequencies. In the present invention, such differences in permittivity and/or permeability are used for the detection and level monitoring of certain fluids and substances in biological tissue.

[41] The studies of the present invention have shown that electromagnetic energy having, for example, a frequency in the range of approximately 300 MHz to approximately 30 GHz (and, more preferably, in the range of approximately 1 GHz to approximately 10 GHz, and, even more preferably, in the range of approximately 3 GHz to approximately 5 GHz) provides good penetration into tissue. In general, such electromagnetic energy is launched into the subcutaneous tissue and a resultant signal is measured. Electromagnetic energy in the frequency range set forth above has been found to transmit through the skin and to transmit or propagate well within, for example, fat. Good transmission through the fat layer is beneficial for detection of extravasation as many extravasations occur in the fat layer. The sensitivity to extravasation of the systems, devices and methods of the present invention is thus increased as compared, for example, to impedance plethysmography. In

the case of impedance plethysmography, the majority of the electrical current passes through highly conductive layers such as skin and muscle in which extravasation is much less likely to occur.

[42] Figure 1A-1E illustrate multiple views of an extravasation sensor according to a presently preferred embodiment of the invention. The extravasation sensor includes a housing, a plurality of antenna or sensor elements, and the RF cable assemblies associated therewith.

[43] The housing is preferably composed of a base material, such as urethane and/or silicone material, into which a ferromagnetic material is mixed. A carbonyl iron powder, such as the EW grade carbonyl iron powder produced by the BASF Corporation, of Mount Olive, New Jersey, is suitable for this purpose. The ferromagnetic powder is mixed into the housing specifically around the antenna elements and cables . A ferromagnetic material with appreciable permeability (e.g., >1), such as the EW grade carbonyl iron powder, will provide a mixture that creates a flexible housing capable of absorbing stray leakage of electromagnetic energy. If not effectively addressed, such leakage could otherwise cause artifacts to be induced within the signals conveyed from the antenna elements due to palpation of the skin in the area of the extravasation sensor or to other movement of the sensor. In addition to motion and palpation artifacts, such leakage could also decrease the sensitivity of the antenna elements to the presence of subcutaneous fluid. It should be apparent that one can also mix the ferromagnetic material into a different base material, one that will form a rigid housing.

[44] Figure 2 illustrates a generalized structural layout for the extravasation sensor of the present invention, one in which four antenna elements are separated to form active and dead zones of operation. In this preferred layout, the dead zone of this Quad Sensor configuration effectively increases the sensing range of the extravasation sensor. Lower sensitivity to small volumes of subcutaneous fluid is achieved by spacing the antenna elements appropriately. This creates a dead zone in which there is decreased sensitivity to fluid. Each pair of antenna elements (i.e., transmitting/receiving antennas designated "A" in Figure 2) forms an "active zone." The active zones are the primary areas in which fluid build up can be detected. The dead zone, however, allows a small, clinically insignificant

amount of fluid (e.g., blood or contrast agent) to collect before the extravasation sensor can detect its presence. This is a particularly desirable feature in the computerized tomography (CT) setting where a small amount of fluid does not require the termination of the CT examination. Furthermore, the volume at which an antenna element begins to become saturated (i.e., at which the signal from an antenna element stops changing) is increased to a larger volume.

[45] Figure 2 also shows that the active and dead zones overlap each other partially. The overlap is due to the fact the extravasation sensor detects fluid accumulation not only directly through permittivity differences between fluid and fat, but also indirectly near an active region (with a decreased signal impact) by sensing the distortion in tissue caused by its presence. Because the active and dead zones overlap each other effectively, the overall fluid volume sensing range is increased significantly with the active/dead zone sensor geometry.

[46] In U.S. Patent Application Publication Nos. 2003/0036674 and 2003/0036713, incorporated herein by reference, the inventor of the present invention disclosed an extravasation detector in which the antenna elements (e.g., patch antenna shown in Figure 7D) were positioned atop or otherwise formed within a substrate and shielded from direct contact with the skin by use of a superstrate. As shown in Figures 1A-1E, however, the extravasation sensor of the present invention can be created with antenna elements that lack a superstrate. Testing has proven that by removing the superstrate an antenna element becomes loaded by the human tissue on which the extravasation sensor is positioned. This serves to increase the bandwidth of the extravasation sensor, which serves to increase its ability to detect subcutaneous pools of various shapes and sizes.

[47] As also noted in the cited publications, each radiating patch antenna element of the invention resides on a substrate (e.g., ceramic material). In the present invention, for each antenna element there is also a conductive front lip on the surface of the ceramic material that provides additional shielding. Coupled with the protection provided by the side shielding disclosed in the cited publications, the conductive lip for each antenna element serves to further decrease the leakage of stray electromagnetic energy.

[48] The cited publications also disclose a variety of antenna elements that are capable of use with extravasation sensors but with various advantages and disadvantages. Not specifically disclosed, however, was a bowtie antenna. Such a bowtie antenna element has been successfully developed for the extravasation sensor of the present invention.

[49] As best shown in Figures 1A-1E and 2, the housing of the extravasation sensor defines a large opening between the antenna elements. This opening provides both visual and tactile (palpation) access to the site of interest where subcutaneous fluid will likely accumulate should extravasation occur. The opening thus provides the operator with the option of checking for or confirming the presence of fluid merely by looking at or palpating the skin through that opening in the housing.

[50] In addition, the housing also features segments that bridge the gap between the antenna elements. These bridge segments are low profile by design to assure that the operator has access through the opening to the site of interest for the purpose of palpation. Nurses or technologists will typically position their hand in such a manner that these low profile bridge segments (those on the sides of the sensor in particular) allow improved ability to palpate the site of interest to check for extravasation. As best shown in Figures 1A and 1C, the side bridges are also curved outwardly away from the center of the palpation area. This also allows increased accessibility.

[51] Figure 3 illustrates a flexible circuit board (also referred to as a "flex circuit") that can be used to carry and distribute the microwave signals being transmitted from and received by the extravasation sensor. More specifically, it features striplines for use in conveying microwave signals to and from the antenna elements of the sensor. As shown, traces with appropriate geometries can be used to split the energy between multiple transmitting and receiving antenna elements if desired. Flex circuit boards and other materials suitable for use at microwave frequencies are commercially available from the Advanced Circuit Materials Division of Rogers Corporation, of Chandler, Arizona.

[52] Figure 4 illustrates a step-by-step procedure for using an attachment mechanism to attach an extravasation sensor of the present invention to the skin of a patient. Designed to be disposable, the attachment mechanism preferably includes a double-sided adhesive

portion and a release band around the perimeter of the adhesive portion. In addition, the adhesive portion defines a cutout region. One side of the adhesive is designed to attach to the skin of the patient over the site of interest, and the opposite side is designed to permit the extravasation sensor to be affixed thereto. When properly applied, the cutout region of the adhesive portion and the opening of the extravasation sensor are coextensive, thereby allowing the operator visual and tactile (palpation) access to the site of interest.

[53] As best shown in Figure 5, the release band enables the operator to pull the attachment mechanism off the skin after use of the extravasation sensor is complete. For ease of use, the color, material or texture of the adhesive portion and the release band are preferably different. This will facilitate the positioning and secure attachment of the extravasation sensor. Each side of the attachment mechanism shown can have two different levels of adhesion (i.e., aggressiveness of adhesive) which will allow the tailoring of the adhesion to the skin side which may be less than that of the sensor side.

[54] As shown in Figures 4, 5 and 6A, the opening for palpation in the housing of the extravasation sensor as well as the cutout region of the attachment mechanism can be formed to indicate the direction to which the sensor should be placed (e.g., arrow shaped). This also helps operator to line up the extravasation sensor and the attachment mechanism for optimal attachment to skin, which is important for integrity of the signals detected and conveyed by the extravasation sensor.

[55] The extravasation sensor of the present invention can also be equipped with one or more user interfaces. Figures 6A and 6B illustrate that light pipes or other visual indicators, such as light-emitting diodes (LEDs), can be incorporated into the extravasation sensor to provide, for example, a visual indication of extravasation. Alternatively, these visual indicators can be incorporated into the RF cable assemblies that interconnect the extravasation sensor and its associated base/control unit. Furthermore, as shown in Figure 6C, a user input button for functions such as "arming" or "baselining" the overall system can be implemented at the extravasation sensor. An audible and/or visual alarm can also be integrated within the housing of the sensor. These features are advantageous because the user often focuses on the injection site (in CT application, for example) and therefore

will not only more readily observe the light indicators situated there but also be more readily disposed to provide input from there.

[56] Such visual/aural indicator devices may alternatively be mounted to or otherwise integrated into a remote display or controller unit for the injector system, such as is illustrated in Figure 5 in the context of a CT imaging suite. Such a remote display or control unit will typically be located in the control room of a CT suite rather than in the scanner room where the injector and extravasation sensor will be sited.

[57] Figure 7 illustrates a system for wirelessly transmitting a signal indicative of extravasation from an extravasation sensor outfitted with a transmitter to a remote receiver. Such a wireless system can be implemented with the extravasation sensor of the present invention. In a presently preferred embodiment, such a wireless system can include an extravasation sensor, a short RF cable, a transmitter and the remote receiver. In use, the extravasation sensor can be attached to, for example, the upper arm about the site of the injection and the transmitter strapped near or directly to the wrist. (If the extravasation sensor is attached to the back of the hand or wrist, the RF transmitter can then be strapped to the upper arm much like a sports radio.) The short RF cable interconnects the two components, and can be either a distinct part or emanate from the housing of the sensor. The short RF cable in this configuration improves performance and decreases motion artifacts and other complications associated with longer cables.

[58] Although the various embodiments and related aspects of the invention herein described and illustrated are presented primarily in the context of CT imaging procedures, the reader should understand that the invention may also be applied or adapted to other types of applications such as positron emission tomography (PET), magnetic resonance imaging (MRI), magnetic resonance angiography (MRA) and ultrasound procedures as well as a wide variety of therapeutic procedures.

[59] The presently preferred embodiment(s) for carrying out the invention have been set forth in detail according to the Patent Act. Persons of ordinary skill in the art to which this invention pertains may nevertheless recognize alternative ways of practicing the invention without departing from the concepts and embodiments disclosed herein.

CLAIMS

What is claimed is:

1. A sensor device for detecting a change in the level of fluid within tissue of a body, the sensor device comprising:

(a) a housing having a plurality of bridge segments, said bridge segments arranged to circumscribe an opening defined by said housing;

(b) a substrate mounted within said housing at least at an intersection of each of said bridge segments; and

(c) a plurality of generally planar antenna elements, each of said antenna elements at a base thereof accommodated by and mounted to said substrate at each of said intersections of said bridge segments and at an outer surface thereof facing away from said substrate;

wherein said housing extends to said outer surfaces of said antenna elements and an electrical shield surrounds each of said antenna elements except for said outer surfaces thereof.

2. The sensor device of claim 1 further including an RF cable assembly for each of said antenna elements, each of said RF cable assemblies at one end thereof including a connector and at the other end thereof molded into said housing and electrically connected to said antenna element corresponding thereto.

3. The sensor device of claim 1 further including an attachment mechanism for enabling the sensor device to be operably attached to the tissue of the body, the attachment mechanism comprising

(a) an adhesive portion defining a cutout region generally coextensive with said opening of said housing, said adhesive portion having one side thereof coated with a first adhesive capable of removably attaching to the tissue and an opposite side thereof coated with a second adhesive capable of attaching to a bottom surface of said housing; and

(b) a release band affixed to a perimeter of said adhesive portion for enabling removal of said attachment mechanism, and the sensor device therewith, from the tissue.

4. The sensor device of claim 3 wherein said first adhesive provides less adhesion than said second adhesive.

5. A system for wirelessly communicating a change in the level of fluid within tissue of a body, the system comprising:

(a) a sensor device for detecting a change in the level of fluid within the tissue;

(b) a transmitter connected to said sensor device for receiving therefrom an indication of the change in the level of fluid within the tissue and for transmitting a radio frequency signal indicative thereof; and

(c) a remote receiver for receiving said radio frequency signal transmitted by said transmitter and for providing a warning alert thereupon.

6. The system of claim 5 wherein said sensor device includes:

(a) a housing having a plurality of bridge segments, said bridge segments arranged to circumscribe an opening defined by said housing;

(b) a substrate mounted within said housing at least at an intersection of each of said bridge segments; and

(c) a plurality of generally planar antenna elements, each of said antenna elements at a base thereof accommodated by and mounted to said substrate at each of said intersections of said bridge segments and at an outer surface thereof facing away from said substrate;

wherein said housing extends to said outer surfaces of said antenna elements and an electrical shield surrounds each of said antenna elements except for said outer surfaces thereof.

7. The system of claim 6 wherein said sensor device further including an attachment mechanism for enabling said sensor device to be operably attached to the tissue of the body, the attachment mechanism comprising

(a) an adhesive portion defining a cutout region generally coextensive with said opening of said housing, said adhesive portion having one side thereof coated with a first adhesive capable of removably attaching to the tissue and an opposite side thereof coated with a second adhesive capable of attaching to a bottom surface of said housing; and

(b) a release band affixed to a perimeter of said adhesive portion for enabling removal of said attachment mechanism, and the sensor device therewith, from the tissue.

8. The system of claim 7 wherein said first adhesive provides less adhesion than said second adhesive.

9. An attachment mechanism for use in attaching a sensing device to the skin of a patient, the attachment mechanism comprising:

(a) an adhesive portion having one side thereof coated with a first adhesive capable of removably attaching to the skin and an opposite side thereof coated with a second adhesive capable of attaching to a bottom surface of said sensing device; and

(b) a release band affixed to a perimeter of said adhesive portion for enabling removal of said attachment mechanism, and the sensing device therewith, from the skin.

10. The attachment mechanism of claim 9 wherein said adhesive portion defines a cutout region generally coextensive with an opening defined by said sensing device.

11. The attachment mechanism of claim 9 wherein said first adhesive provides less adhesion than said second adhesive.

ABSTRACT

A sensor device enables changes to be detected in the level of fluid within tissue of a patient. The sensor device includes a housing, a substrate, and a plurality of antenna elements. The housing has a plurality of bridge segments that are arranged to circumscribe an opening defined by the housing. The substrate is mounted within the housing at least at an intersection of each of the bridge segments. Each of the antenna elements at a base thereof is accommodated by and mounted to the substrate at each of the intersections of the bridge segments and at an outer surface thereof faces away from the substrate. The housing extends to the outer surfaces of the antenna elements and an electrical shield surrounds each of the antenna elements except for the outer surfaces thereof.

FIGURE 1A

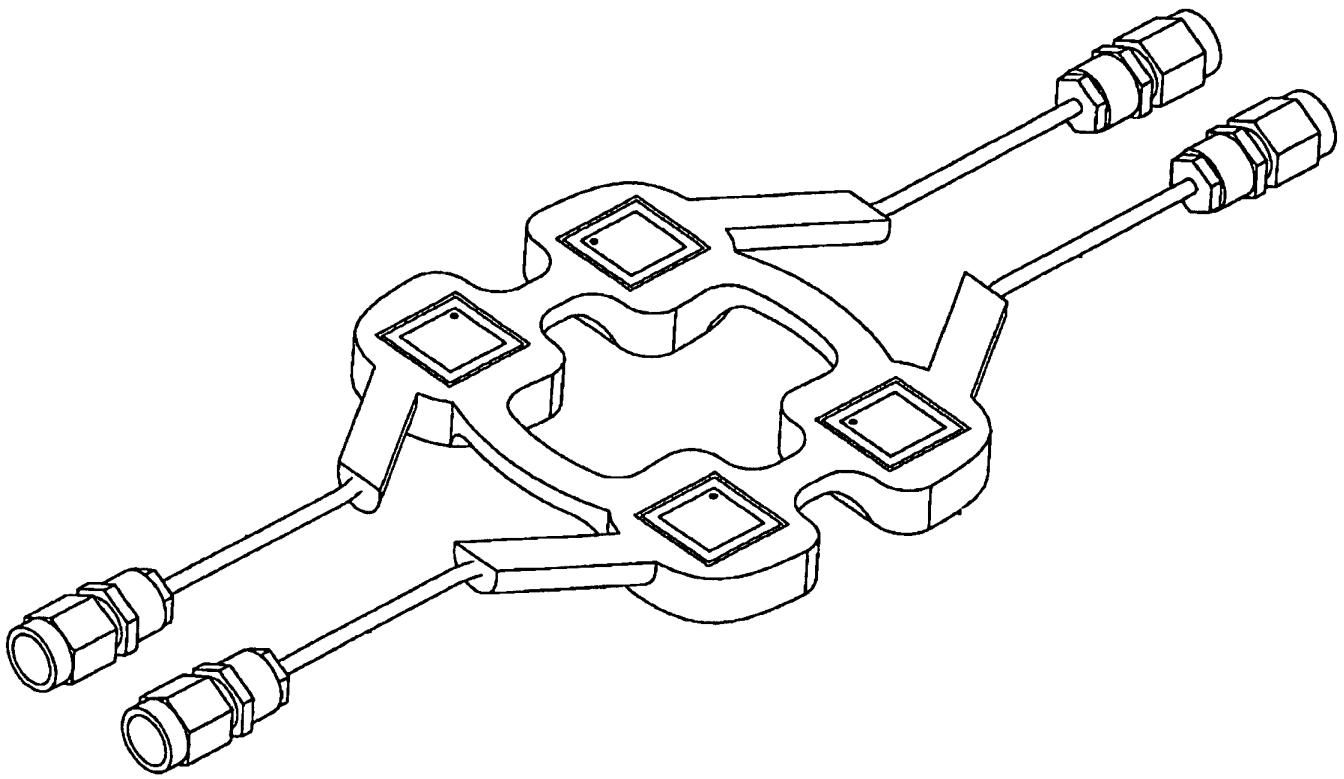


FIGURE 1D

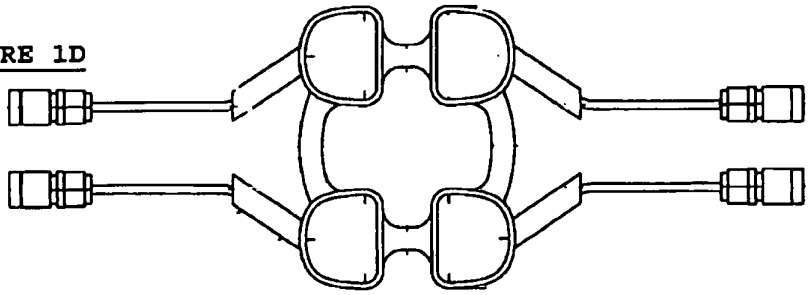


FIGURE 1C

FIGURE 1E

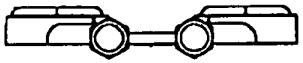


FIGURE 1B

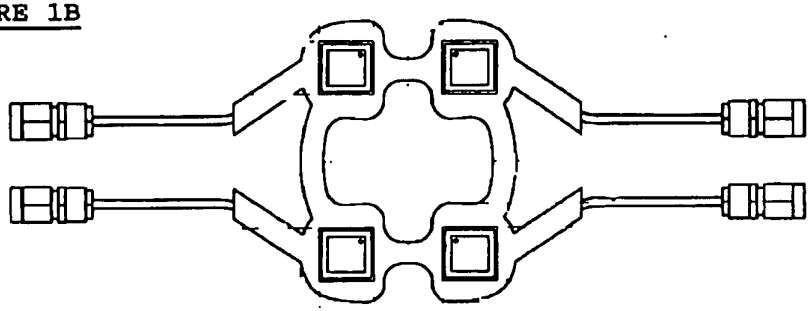
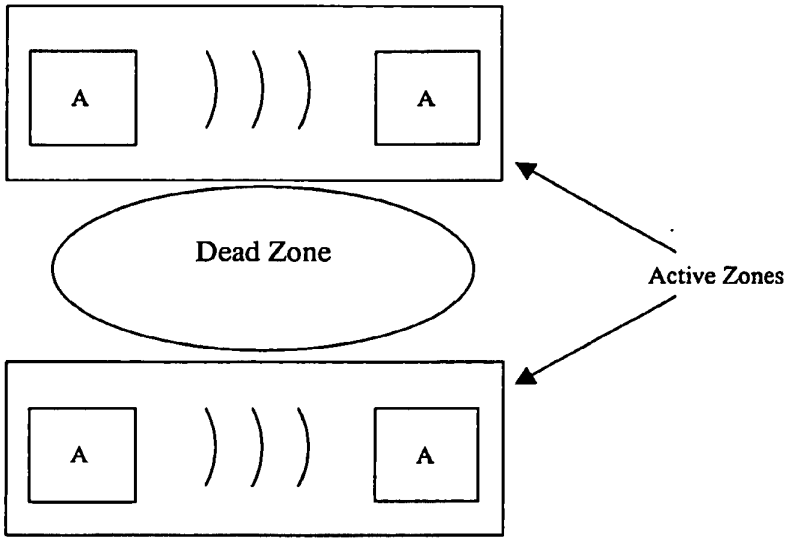


FIGURE 2



(Top View of Sensor on Surface of Skin)

Exploring Potential Sensor Manufacturing Techniques

- Using Flexible Striplines for Distribution and Connection to Transmitting/Receiving Antennas

Addresses not only distribution need, but also <u>antenna feed attachment</u> (currently soldered by hand)

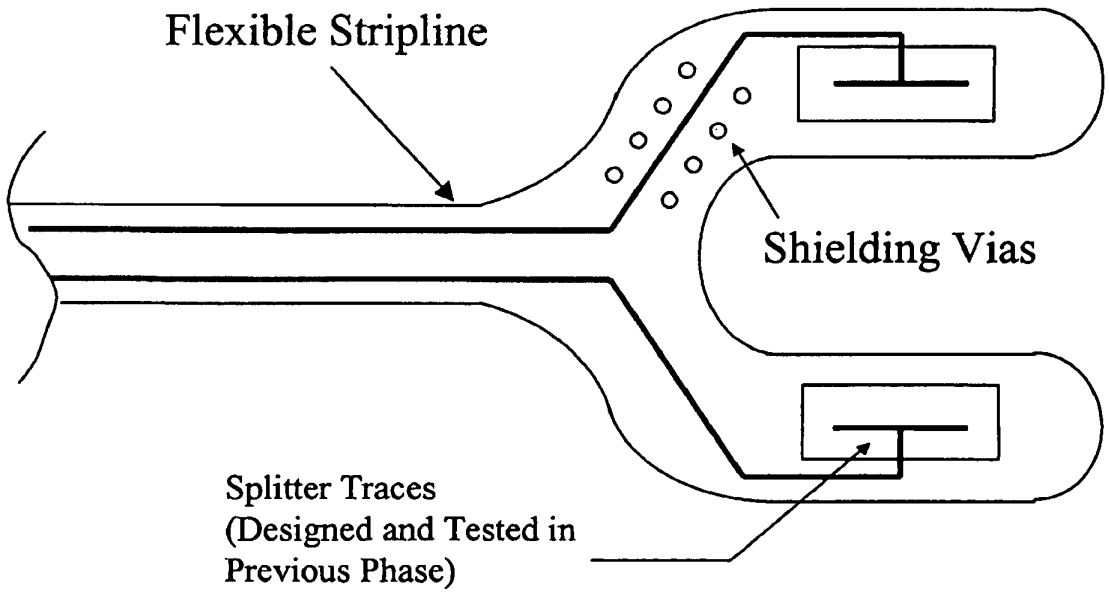
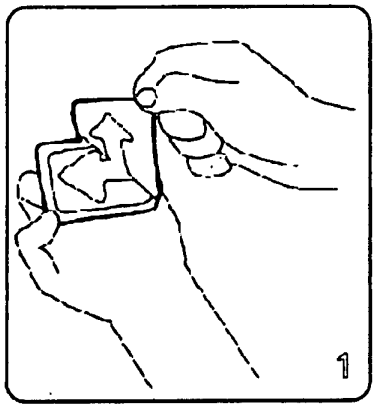
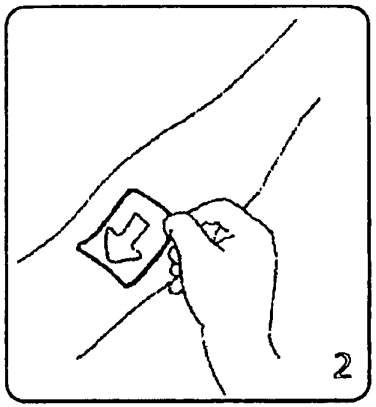
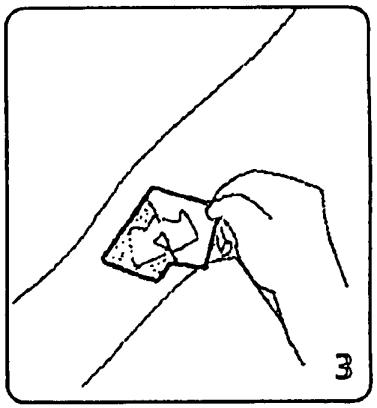


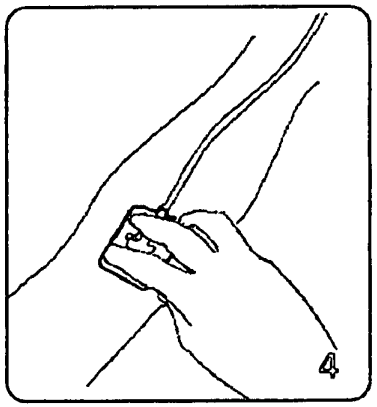
FIGURE 3

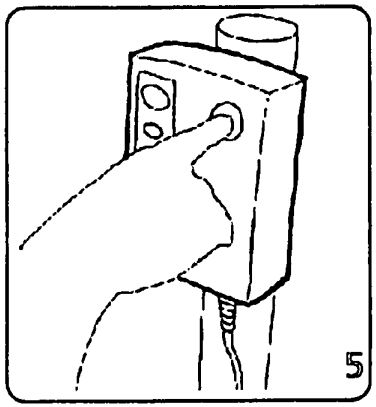
FIGURE 4







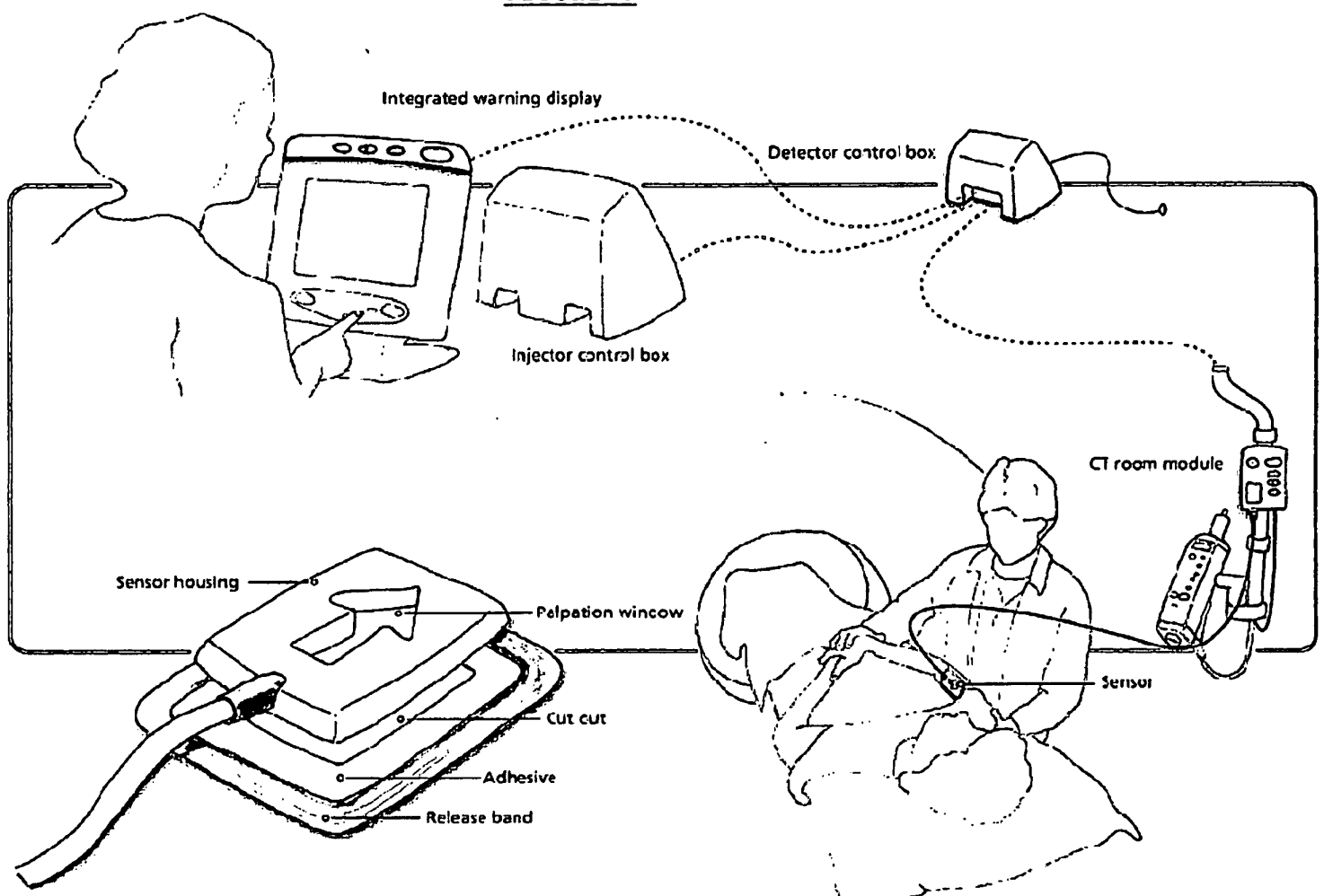




Application steps

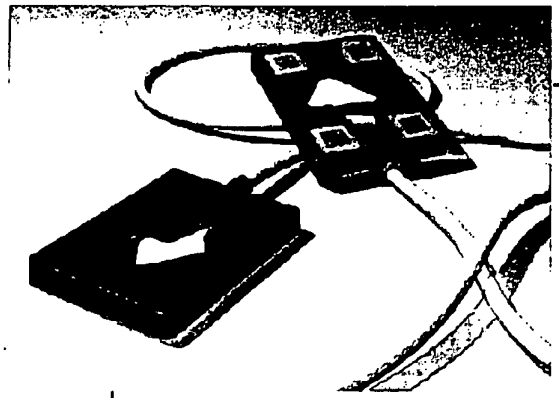
medrad®
Business Sensitive

FIGURE 5



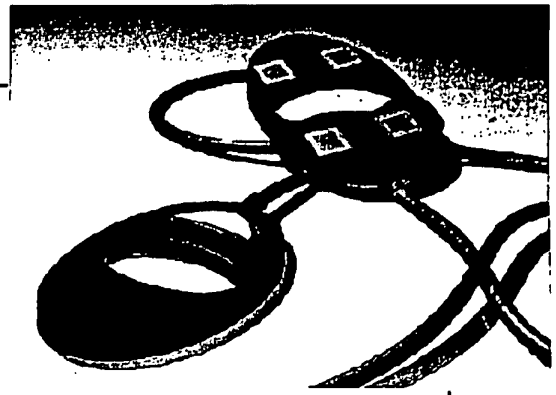
Green=System ready
Red = Error
Blue = Offline

FIGURE 6A

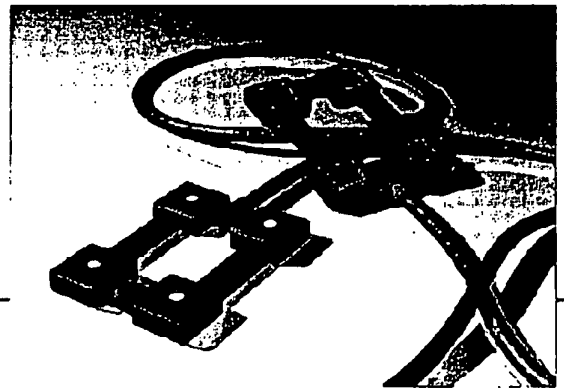


Light Pipes

FIGURE 6B



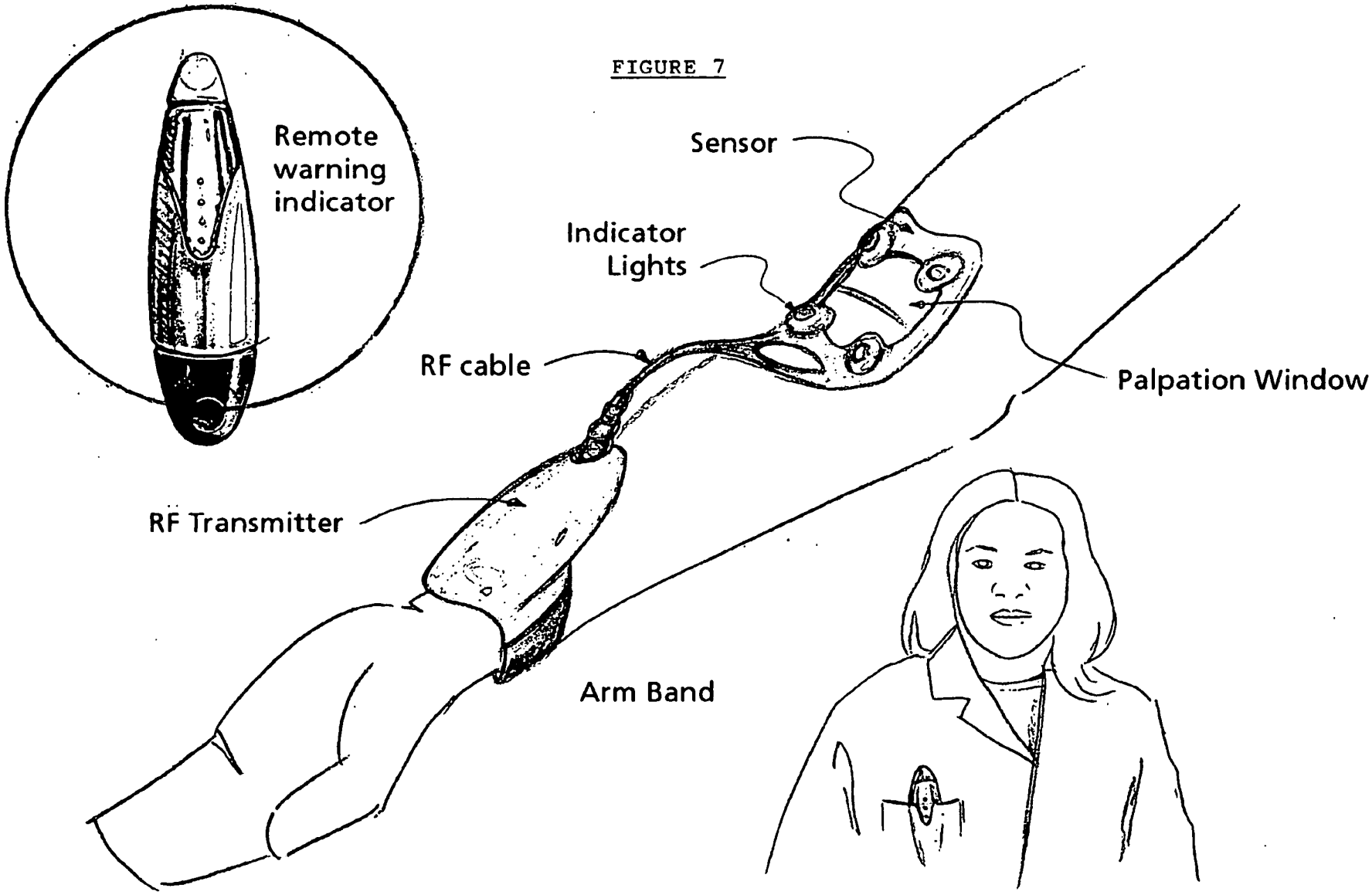
Arm button/ Alarm indicator



Individual sensor lights

FIGURE 6C

FIGURE 7



Remote warning indicator worn by technician

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